

**REMARKS**

**I. Amendments and Status of the Claims**

Claims 10-14 and 17-22 were previously pending.

Applicants acknowledge with appreciation that the Office has withdrawn all prior rejections in this case. The Office also indicates that claims 13-14 and 22 would be allowable if rewritten in independent form. Office Action, page 2. Applicants have amended claim 10 to incorporate the subject matter of claim 13. Thus, amended claim 10 corresponds to claim 13 rewritten in independent form. In addition, Applicants have cancelled claim 13, amended claim 14 to depend from claim 10, and rewritten claim 22 in independent form. Support for the amendments is found in the original claims and throughout the specification. These amendments add no new matter.

Claims 10-12, 14, 17-19, and 22 remain pending and under consideration. The Office has withdrawn claim 18 with respect to the recitation of an adjuvant that is a sugar or alcohol, and claims 20 and 21 as being drawn to non-elected species. Office Action, page 2. Applicants respectfully request the Office rejoin the withdrawn claims and extend the search to the remaining species in view of the following response.

**II. Rejections Under 35 U.S.C. § 102**

The Office rejects claims 10 and 11 under 35 U.S.C. § 102(b) and 102(e) as allegedly anticipated by U.S. Patent No. 5,871,464 to Tryggvason et al. ("Tryggvason"). Office Action, pages 3, 4. Applicants respectfully traverse the rejections.

As an initial matter, Applicants note that this application claims benefit of priority of U.S. provisional application No. 60/132,120, filed April 30, 1999. Tryggvason issued

on February 16, 1999, which is a date less than one year before Applicants' earliest effective filing date. Tryggvason, therefore, is not available as a reference under 35 U.S.C. § 102(b), and the rejection under 35 U.S.C. § 102(b) should be withdrawn.

To anticipate a claim under 35 U.S.C. § 102, every element recited in the claim must be disclosed in the reference. See *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.") Although Applicants have amended claim 10 in order to expedite prosecution, they note that the description of the adenoviral stocks in Tryggvason does not require that the buffer solution does not contain added divalent metal cations or alkali metal cations. As the specification discusses in the paragraph bridging pages 2-3, the tris-based formulations described in the literature systematically contained magnesium chloride and/or a salt. Thus, Tryggvason's silence regarding the inclusion of divalent metal cations or alkali metal cations in the adenoviral preparations cannot be taken to indicate that the buffer solution does not contain added divalent metal cations or alkali metal cations. Further, the Office provides no evidence that, unlike usual adenoviral formulations, the adenoviral preparation of Tryggvason does not contain added divalent metal cations or alkali metal cations.

The Office has failed to establish that Tryggvason teaches all elements of the claims. Applicants therefore respectfully submit that the rejection of record was in error. Nevertheless, Applicants have amended claim 10 to recite the language previously recited in claim 13, which the Office has indicated is allowable. Claim 11 depends from

amended claim 10, and Applicants submit that the rejection of record is therefore also inapplicable to pending claim 11.

**III. Rejection Under 35 U.S.C. § 103(a)**

Claims 10, 12, 17, 18, and 19 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,871,464 to Tryggvason et al.

("Tryggvason") taken with WO98/02522 to Sene et al. (English equivalent, U.S. Patent No. 6,451,256 to Sene et al.) ("Sene"). Office Action, page 5. Applicants traverse the rejection.

To establish a *prima facie* case of obviousness, the Office bears the burden of showing that the combination of references teach or suggest all of the claim limitations. M.P.E.P. § 2143; *In re Royka*, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974). As noted in Section II, Tryggvason does not teach each element of claim 10. Combining Sene with Tryggvason does nothing to remedy the defects in the primary reference. Instead, Sene teaches that it is desirable to include salts of divalent cations, such as magnesium, which is an alkaline earth metal. Sene, col. 3., lines 18-22. Further, Sene teaches that glycerol is irritating to pulmonary epithelium and goes on to state that one advantage of Sene's invention is to provide a composition that avoids the inclusion of irritants (i.e., glycerol). See Sene, col. 2, lines 5-9 and 37-47. It is improper to combine references where the references teach away from their combination. M.P.E.P. § 2145.I.X.D.2 (citing *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983)). Here, the claims recite "a composition comprising adenovirus, a Tris/HCl buffer solution, and glycerol, wherein said buffer solution does not contain added divalent metal cations

or alkali metal cations . . . .” Sene, therefore, cannot properly be combined with the teachings of Tryggvason because Sene teaches away from the claimed compositions.

Applicants further traverse the Office’s position that the ordinary artisan would have been motivated to combine the teachings of Tryggvason and Sene to formulate the compositions recited in claims 17-19. Those claims depend directly or indirectly from claim 10 and so also require that the composition contain glycerol and that the buffer solution does not contain added divalent metal cations or alkali metal cations.

For these reasons, Applicants submit that the Office has failed to establish a *prima facie* case of obviousness. Applicants therefore respectfully request the Office to withdraw this rejection.

### **CONCLUSION**


In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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